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Abstract

Following the Vietnam War concern regarding the association of military exposures and birth defects has grown. The possibility of such associations remains a source of unease. In order to determine if such an association exists, birth defects surveillance among military families must be conducted. This project compared health record abstraction (active surveillance) with screening of Department of Defense electronic medical data (passive surveillance) to detect birth defects among San Diego County military families during the period January 1, 1997 through June 30, 1998. A total of 171 of 5351 infants (3.2%) were identified as having a major defect, consistent with national civilian rates. There was approximately 80% concurrence between passive and active surveillance birth defect data, suggesting that use of a hybrid system of electronic data, supplemented with active surveillance in a specific region, is a feasible and cost-effective surveillance program for the geographically dispersed military population.

(147 words)

Introduction

Birth defects, responsible for 21% of infant deaths in the United States, are the leading cause of infant mortality, and the sixth leading cause of potential life lost.[1, 2] Following the Vietnam War, concern regarding the association of military exposures and birth defects has grown. To determine if such an association exists, it is important to gather birth defects statistics among military dependents.

Although neither a DoD nor a national US birth defects registry currently exists, 31 states have established birth defects registries.[3] These registries collect International Classification of Disease, Ninth Revision (ICD-9) codes and demographic information such as date and place of birth as well as sex of the infant. This surveillance often leads to epidemiological studies, public health interventions to reduce morbidity, and improved prenatal care.[4-6]

State registries, cannot adequately monitor defects among military families, because few states have access to data from military hospitals.[7] Frequently, civilian hospital data cannot be readily linked to US military populations because few registries collect personal identifying information such as parental or infant social security numbers and confidentiality laws prevent using the social security number as a linkage tool in those states that do.

Given the incapacity of civilian systems to provide military beneficiary information, it is important to build a military birth defects surveillance system. Such a system will provide the data needed to answer questions regarding birth defect prevalence in this special population. With more than 78,000 military births a year, the surveillance will also help to provide the information needed to create a more accurate national profile of birth defects.

Methods

Study Subjects

This study was conducted in compliance with Department of the Navy use of human subjects protocols and regulations. Because miscarriages, especially those occurring early in the pregnancy, stillbirths, and induced abortions are not uniformly diagnosed and recorded, the denominator for this population was limited to livebirths. The population included all San Diego County DoD beneficiaries' livebirths from January 1, 1997 through June 30, 1998.

Reproductive Health Care for DoD Beneficiaries

The DoD provides medical care for active-duty personnel, dependents of active-duty personnel, retirees and their beneficiaries, and survivor beneficiaries. Dependents must be enrolled in the Defense Enrollment Eligibility Reporting System (DEERS) to receive care. The obstetric services of military facilities are restricted to active-duty military (defined as regular active duty, cadet/midshipman, guard/reserve) and their dependents. In San Diego County the majority of military births take place in one of two military facilities: Naval Medical Center San Diego, which is a tertiary referral center for TriCare Region Nine and the largest military hospital in the United States (500 beds), and Naval Hospital Camp Pendleton, a 180-bed hospital serving a large US Marine Corps population in northern San Diego County. The remaining military births are cared for by a cost-sharing health insurance program, Civilian Health and Medical Program of the Uniformed Services (CHAMPUS).

Birth Defect Case Definition

An infant with a birth defect was included as a case if the following criteria were met: (1) at least one parent had a residential zip code in San Diego County; (2) the infant's date of birth occurred between January 1, 1997, and June 30, 1998; and (3) the infant was diagnosed with at least one birth defect from the Metropolitan Atlanta Congenital Defects Program (MACDP) list,[8] which includes more than 1000 major and minor defects. A birth defect was classified as *major* if it was 1 of the 37 specific defects so labeled in a previous DoD birth defects study.[9] Although laboratory and chromosomal confirmation of diagnoses were recorded for certain genetic disorders, most diagnoses of birth defects were based solely on clinical features.

<u>Data Sources</u>

Active surveillance. The medical records department staff at both study sites were requested to identify patient records containing specific ICD-9 codes that fit the MACDP list, as well as procedure codes such as cardiac catheterization that might indicate a birth defect. These departments used the Composite Health Care System (inpatient) and the Ambulatory Data System (outpatient) to search for probable cases. Subspeciality clinic logs, such as surgery, were also reviewed for possible cases. Once these probable cases were identified, their medical charts were pulled and reviewed by study staff. If necessary, related charts were requested. Birth defect, demographic, prenatal, and postnatal data were gathered from the child=s medical charts (inpatient and outpatient). The mother=s inpatient and outpatient medical charts were reviewed for obstetric history, follow-up care, subsequent diagnoses, and general course of care. The infant=s outpatient chart permitted the tracking of defects over the first year of life.

Passive surveillance. The Corporate Executive Information Systems (CEIS) database, containing inpatient encounters in military treatment facilities, and an electronic CHAMPUS billing records database, containing civilian medical facility encounters, were searched for all health care encounters with ICD-9-CM birth defects from the MACDP list. These data were organized and evaluated with the same case criteria as the active surveillance. Those data that were determined to have met the case criteria were linked to demographic information and individual profiles entered in the registry.

Quality Control

To ensure quality data collection, a consultant from the Centers for Disease Control and Prevention trained the abstracters in case-finding methodology and data recording and they were supervised throughout the project. Data range checks and summary database reports were used to further examine the quality of the data.

The active surveillance data were used to measure the completeness and accuracy of the passive surveillance data. This validation procedure was performed on all of the CEIS data as well as the subset of individuals who obtained their CHAMPUS benefits in a military facility.

Statistical Analyses

An infant was counted only once for each diagnostic code, regardless of the number of medical encounters he or she may have had for the defect. Once the total number of cases in each of the three databases (active surveillance, CEIS, CHAMPUS) was tabulated, the data were combined, and the total number of unique infants with birth defects was determined. DEERS census data were used as

the denominator for the overall major birth defects prevalence. A number of organ category and specific diagnosis prevalence statistics were also calculated. Because of the limited size of the population and the duration of the study, statistical tests of association were not conducted.

Results

From San Diego County, a total of 5351 children with a date of birth between January 1, 1997, and June 30, 1998, were added to DEERS and this figure was used as the denominator for all rate calculations. Among the 5351 infants born in the San Diego region during the 18-month period, 615 (11.5%) had a birth defect and 171 (3.2%) had a major birth defect. A comparison of the three databases categorized by organ system revealed a difference in the type of birth defects each system identified (Table 1). The passive CEIS surveillance detected fewer cleft palate/lip, upper alimentary, male reproductive, and urinary tract birth defects than the active surveillance database.

Prevalence for the composite (total unique infants with major birth defects) birth defects registry and 95% confidence intervals are presented in Table 2. Cardiovascular defects were the most common defects in this population. The birth defects registry data were further stratified by individual ICD-9-CM codes (Table 3). The three most common defects were ventricular septal defect, hypospadias and epispadias, and obstructive genitourinary defect.

When the active surveillance and the CEIS data for all birth defects were stratified by 3-month periods — January-March 1997, April-June 1997, and July-September 1997 (all of which were 90% complete) — there was 72% agreement between the sources (data not shown). The agreement for the second three quarters of the study was less than 50%, demonstrating the amount of time necessary for

a case to enter the passive system. It is estimated that when more complete CEIS data are available agreement will be approximately 80%.

Discussion

This composite birth defects registry yielded a major (those defects that affect survival, require substantial medical care, or result in marked physiological or psychological impairment)[1] birth defects prevalence of 3.2%, which is consistent with national prevalence.[1,10,11] We have demonstrated that it is possible to conduct both active and passive surveillance for births occurring in a DoD beneficiary population. The associations between occupational exposures with birth defects are of particular interest to military public health officials. Data similar to these are necessary for determining the strength of the associations of birth defects and maternal infections,[10, 12, 13]; maternal lifestyle,[14-18]; parental age [19, 20]; and exposure to various reproductive toxins.[21, 22]

Conducting birth defect surveillance raised important confidentiality issues regarding the inclusion of personal identifiers, an issue that will continue to be debated as more and more medical records are computerized. Following a comprehensive review of the issues, our institutional review board (the Committee for the Protection of Human Subjects) decided that this study met the definition of surveillance and intrinsic to surveillance was the need to examine such data. A more definitive directive, regulation, or law, however, would certainly aid public health practitioners in future data collection.

This pilot project had a number of limitations. Birth defects registries must often contend with the time lag that occurs between recognition of the defect and its inclusion in the registry. This delay may impede rapid identification of important clusters of birth defects cases. In some instances there

was an 18-month lag period between the medical encounter and its entry into CEIS. This time lag may explain why the passive CEIS surveillance contained a smaller number of cleft palate/lip, upper alimentary, male reproductive, and urinary tract birth defects than the active surveillance database.

When the active surveillance and the CEIS data were stratified by 3-month periods —January-March 1997, April-June 1997, and July-September 1997 (all of which were 90% complete) — there was 72% agreement between the sources. The efficiency of the reporting improved, however, during our data collection; near the conclusion of our work, many of the electronic data were merely weeks old.

These data are further limited by the accuracy of numerator and denominator data. Only livebirths were included in our denominator. An estimated 22% of pregnancies are lost subclinically and an estimated 15-20% of recognized pregnancies result in spontaneous abortion.[23] Such early pregnancy losses may reflect nonviability of the fetus due to chromosomal anomalies (these infants would have had birth defects had they survived to term). Consequently, our rates reflect the livebirth/defect relationship rather than the pregnancy/defect relationship, which would be a more useful relationship for identifying clusters or other trends. Finally, our data were limited to birth defects detected within the first year of life.[1] While approximately 95% of structural birth defects are recognized by a child's first birthday,[24] those defects detected after 1 year of age were not included.

There are limitations in working with data sets that have been collected for reasons other than clinical research. For example, CHAMPUS data do not contain a variable for race or ethnicity, and these data must be matched with DEERS demographic data. Additionally, because no civilian medical charts were available for review, CHAMPUS electronic data could not easily be validated or supplemented.

Although some individuals appear in all three databases, total agreement among the databases is unlikely. The active surveillance and the CEIS collection methods should have a high percentage of agreement because they are focused on the same population. The CHAMPUS database, however, includes many individuals seen by civilian health care providers. These individuals will not be part of the active surveillance or the CEIS catchment.

Using existing vital records, such as birth and death certificates, to identify possible missed cases was deemed inefficient. The amount of information this process would have yielded was determined to be insignificant when evaluated in terms of the time and the resources it required. The New York Congenital Malformations Registry matched vital records to its registry to identify unreported cases. The staff found that this technique increased the statewide prevalence of major malformations by 1.7%, from 416.5 to 423.4 per 10,000 livebirths. That registry concluded the small number of identified new cases did not justify the amount of resources used to augment the registry.[25] Moreover, unlike the New York population, all Navy beneficiaries have to be registered with DEERS in order to receive health care. Given the availability of this data source, sorting through vital records was deemed unnecessary.

Finally, there are data limitations particular to military health care. In the military system, medical charts are often moved from facility to facility as service members are transferred. Thus, paper medical charts needed for abstraction are not always available. The variability of coding procedures may also affect case ascertainment. In the past, military hospitals have not used the same diagnostic coding procedures as civilian, revenue-based hospitals use. Because of recent changes in military medical management, diagnostic coding procedures are now more consistent with those of civilian hospitals. The quality of these data will continue to improve in the future.

Conclusions

Realizing that military families are located in many disparate geographical areas and that personnel resources necessary for active surveillance are quite expensive, we considered the effectiveness of combining components of active and passive birth defects surveillance in a hybrid system. A passive database screening system with a sensitivity of 80% might be combined with a regional active surveillance system. The active surveillance would permit the collection of comprehensive data not available in the passive system and serve as a validation tool. Such a hybrid system would require minimal personnel resources, yet would provide important national DoD data to policy makers.

If surveillance for birth defects among military beneficiaries is extended over a period of many months or years, it will be possible to use these data to detect clustering, to monitor temporal trends, and to project future morbidity.

This project demonstrated the feasibility of conducting regional DoD surveillance for birth defects among infants of military beneficiaries. Because of the success of this project, the DoD has recently endorsed a 5-year project to conduct DoD-wide birth defects surveillance among DoD health care beneficiaries. Using a hybrid method of active surveillance and passive surveillance using electronic data, the registry will be maintained at the Naval Health Research Center, San Diego. These birth defects rates estimates will provide an important foundation for DoD reproductive health policy decisions.

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Table 1. Comparison of Major Birth Defects Surveillance Methods, January 1, 1997 – June 30, 1998*

Defect Category	Active Surveillance	Passive CEIS Surveillance	Passive CHAMPUS Surveillance	Unique Infants With Major DefectsH
Nervous system	5	6	6	15
Eye	2	0	2	4
Ear	1	0	0	1
Cardiovascular	33	29	8	63
Respiratory	4	3	0	4
Cleft palate/lip	12	4	3	14
Upper alimentary	9	5	0	11
Digestive	4	2	1	5
Male reproductive	25	7	0	29
Urinary tract	23	10	1	25
Musculoskeletal	3	5	1	9
Limbs	2	0	0	2
Chromosomal anomalies	7	4	3	10
Total	130	75	25	192

* N = 5351 livebirths.

H Some infants with birth defects were detected by more than one surveillance method.

Table 2. Prevalence of Major Birth Defects, by Organ System, January 1, 1997 – June 30, 1998, San Diego Country Military Beneficiaries*

Defect Category	**Infants**H	**% Category**	**Prevalence**I	**95% CI**
Nervous system	15	7.8	2.8	1.4-4.2
Eye	4	2.1	0.7	0.0-1.5
Ear	1	0.5	0.2	0.0-0.6
Cardiovascular	63	32.8	11.8	8.9-14.7
Respiratory	4	2.1	0.7	0.0-1.5
Cleft palate/lip	14	7.3	2.6	1.2-4.0
Upper alimentary	11	5.7	2.1	0.8-3.3
Digestive	5	2.6	0.9	0.1-1.8
Male reproductiveэ	29	15.1	5.4	3.5-7.4
Urinary tract	25	13.0	4.7	2.8-6.5
Musculoskeletal	9	4.7	1.7	0.6-2.8
Limbs	2	1.0	0.4	0.0-0.9
Chromosomal anomalies	10	5.2	1.9	0.7-3.0

* N = 5351 livebirths

H Some infants are cases in more than one category.

I Prevalence expressed per 1000 livebirths.

э Female reproductive birth defects do not have a category within the rubric of major birth defects.

Table 3. Prevalence of Major Birth Defects by Specific Birth Defect in San Diego Military Beneficiaries*

Organ System	Birth Defect	ICD-9-CM Codes	CasesH	PrevalenceI
Nervous system	Anencephaly	740.0, 740.1	0	Not app
	Spina bifida without anencephaly	741.1, 741.9 without 740.0 – 740.10	0	Not app
	Hydrocephaly without spina bifida	742.3 without 741.9	11	2.1
	Enephalocele	742.0	0	Not app
	Microcephalus	742.1	7	1.3
Eye	Anophthalmia/microphthalmia	743.0, 743.1	8	1.5
	Congenital cataract	743.30 – .34	12	2.2
	Aniridia	743.45	0	0
Ear	Anoia/microtia	744.01, 744.23	1	0.2
Cardiovascular	Common truncus	745.0	0	Not app
	Transposition of great arteries	745.10 – .12, 745.19	3	0.6
	Tetralogy of Fallot	745.2	9	1.7
	Ventricular septal defect	745.4	30	5.6
	Atrial septal defect	745.5	18	3.4
	Endocardial cushion defect	745.60 – .61, 745.69	6	1.1
	Pulmonary valve atresia and stenosis	746.01, 746.02	19	3.6
	Tricuspid valve atresia and stenosis	746.1	0	Not app
	Ebstein's anomaly	746.2	2	0.4
	Aortic valve stenosis	746.3	3	0.6
	Hypoplastic left heart syndrome	746.7	3	0.6
	Coarctation of aorta	747.10	5	0.9
	Pulmonary artery anomalies	747.3	11	2.1

Organ System	Birth Defect	ICD-9-CM Codes	CasesH	PrevalenceI
Respiratory	Choanal atresia	748.0	0	Not app
	Lung agenesis/hypoplasia	748.5	4	0.7
Cleft palate/lip	Cleft palate without cleft lip	749.00-.04	9	1.7
	Cleft lip with and without cleft palate	749.1, 749.2	4	0.7
Upper alimentary	Esophageal Atresia/tracheoesophageal fistula	750.3	0	0
	Pyloric stenosis	750.5	11	2.1
Digestive	Rectal and large intestinal atresia/stenosis	751.2	2	0.4
	Hirschsprung's disease (congenital megacolon)	751.3	2	0.4
	Biliary atresia	751.61	1	0.2
Male reproductive§	Hypospadias and epispadias	752.6	29	5.4
Urinary tract	Renal agenesis/hypoplasia	753.0	2	0.4
	Bladder exstrophy	753.5	1	0.2
	Obstructive genitourinary defect	753.2, 753.6	23	4.3
Limb	Reduction deformity, upper limbs	755.20 – .29	1	0.2
	Reduction deformity, lower limbs	755.30 – .39	1	0.2
Musculoskeletal	Congenital hip dislocation	754.30, 754.31, 754.35	10	1.9
	Gastroschisis/omphalocele	756.7	16	3.0
	Diaphragmatic hernia	756.6	6	1.1
Chromosomal	Trisomy 13	758.1	2	0.4
	Down's syndrome	758.0	11	2.1
	Trisomy 18	758.2	0	Not app

* N = 5351 livebirths.

H Some individuals had more than one defect.

I Prevalence is expressed per 1000 livebirths.

§ Female reproductive birth defects do not have a category within the rubric of major birth defects.

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Abstract
Following the Vietnam War concern regarding the association of military exposures and birth defects has grown. The possibility of such associations remains a source of unease. In order to determine if such an association exists, birth defects surveillance among military families must be conducted. This project compared health record abstraction (active surveillance) with screening of Department of Defense electronic medical data (passive surveillance) to detect birth defects among San Diego County military families during the period January 1, 1997 through June 30, 1998. A total of 171 of 5351 infants (3.2%) were identified as having a major defect, consistent with national civilian rates. There was approximately 80% concurrence between passive and active surveillance birth defect data, suggesting that use of a hybrid system of electronic data, supplemented with active surveillance in a specific region, is a feasible and cost-effective surveillance program for the geographically dispersed military population.

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